



Prairie

EDUCATION & RESEARCH COOPERATIVE

326 North 7th Street, Suite 101, Springfield, IL 62701 • (217) 544-6464 X 66044 • Fax: (217) 522-1206

RESPECT

<u>Trial Sponsor:</u>	Medtronic Cardiac Rhythm Disease Management
<u>Principal Investigator:</u>	Luis Caceres, MD
<u>Trial Name:</u>	Reducing Episodes by Septal Pacing Efficacy Confirmation Trial (RESPECT)
<u>Purpose:</u>	The purpose of this study is to find out if specialized programs in the AT500 and EnRhythm pacemakers will reduce the number of irregular heartbeat in the upper chamber of the heart and reduce symptoms (such as shortness of breath, dizziness, and others).
<u>Study Type:</u>	Interventional
<u>Study Design:</u>	Prevention, Randomized, Single Blind, Active Control, Crossover Assignment, Efficacy Study
<u>Expected Enrollment:</u>	400
<u>Study Start:</u>	February 2004

Primary Outcome Measures:

- Symptom frequency caused by irregular heartbeats originating from the top heart chambers

Secondary Outcome Measures:

- Subject symptoms
- Time to first cardioversion (changing an abnormal heart rhythm into a normal one by using either medication or electrical shock)
- Specialized pacing feature effect on atrial tachyarrhythmia/atrial fibrillation (AT/AF) in different groups of people



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Eligibility:

Genders Eligible for Study: Both

Inclusion Criteria:

- Subjects with fast and/or slow heartbeats who are in need of dual chamber pacing (pacing in both the atria and ventricles) as determined by their doctor.
- Subjects who have a history of occasional fast heartbeats originating from the upper heart chambers.
- Subjects who have experienced at least two symptomatic episodes of fast heartbeats three months prior to enrollment.
- Subjects that are expected to stay on the same heart medications during the length study.

Exclusion Criteria:

- Subjects who have permanent (chronic) or persistent (not self-terminating) atrial fibrillation (fast heartbeats originating from the upper heart chambers).
- Subjects who have atrial fibrillation due to a reversible cause, i.e. electrolyte imbalance.
- Subjects who are current or immediate implantable cardioverter defibrillator (ICD) recipients.